

In re of Application of: Haiyin HE, et al.  
Application No.: To be assigned      Group No.: To be assigned  
Filed: To be assigned      Examiner: To be assigned  
For: ANTIBIOTIC CYAN 426-A  
Confirmation No.: To be assigned  
Customer Number: 25291

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

December 15, 2003

DECLARATION OF DANIEL B. MORAN

Sir:

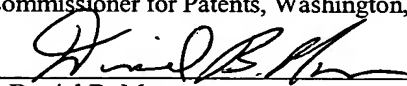
I, DANIEL B. MORAN, hereby declare and state:

1. I am the agent of record in the above-captioned application in which I represent the inventors.
2. Attached to this Declaration is what I am informed and I believe is a true copy of the deposit application papers dated October 29, 2002 which accompanied the deposit of Unidentified fungus, strain designation Cyan-426, said deposit having been made on October 30, 2002 with Agricultural Research Services Culture Collection (NRRL), National Center for Agricultural Utilization Research, Agricultural Research Service, U.S. Department of Agriculture at 1815 North University Street, Peoria, IL 61604.

**CERTIFICATE OF MAILING 37 CFR §1.10**

I hereby certify that this paper and the documents referred to as enclosed therein are being deposited with the United States Postal Service on the date written below in an envelope as "Express Mail Post Office to Addressee" Mailing Label Number EU673382032US addressed to the Commissioner for Patents, Washington, DC 20231.

December 15, 2003  
Date

  
Daniel B. Moran

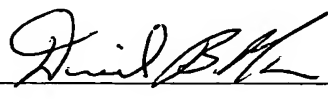
3. Attached to this Declaration is what I am informed and I believe is a true copy of a Receipt dated December 17, 2002 of a deposit of biological material made by applicants, which are relevant to the above captioned application, namely:

Unidentified fungus, strain designation Cyan426, said deposit having been made on October 30, 2002 with Agricultural Research Services Culture Collection (NRRL), National Center for Agricultural Utilization Research, Agricultural Research Service, U.S. Department of Agriculture at 1815 North University Street, Peoria, IL 61604.

4. Attached to this Declaration is what I am informed and I believe is a true copy of a Receipt dated December 17, 2002 that said deposit was tested and found to be viable on November 14, 2002, and was accorded accession number NRRL 30632.

5. The Agricultural Research Services Culture Collection (NRRL), is an International Depository Authority under the Budapest Treaty. The deposit NRRL 30632 has thus been accepted by an International Depository Authority under the provisions of the Budapest Treaty. In accordance with the terms of the Budapest Treaty, all restrictions upon the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent on this application and the deposits will be replaced if viable samples cannot be dispensed by the depository. The deposited materials will be maintained for a period of at least 30 years after the date of deposit, or five years after the most recent request for a sample, whichever is longer.

6. I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the instant patent application or any patent issuing thereon.

Date December 15, 2003 Daniel B. Moran 

**AGRICULTURAL RESEARCH SERVICE CULTURE COLLECTION (NRRL)**  
**(International Depositary Authority)**

National Center for Agricultural Utilization Research  
 Agricultural Research Service, U.S. Department of Agriculture

1815 North University Street, Peoria, Illinois 61604 U.S.A.

ADDRESS SHIPMENTS AND FORMS TO MR. J. L. SWEZEY AT ABOVE ADDRESS  
**MICROORGANISM DEPOSIT UNDER THE BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION  
 OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE**  
**(Budapest Treaty)**

THIS BOX FOR NRRL USE ONLY	
Date and Nature of Material Received:	
Date Deposit Accessioned:	
as NRRL No:	
(Contingent on depositor's verifying acceptability of Agricultural Research Service Culture Collection (NRRL) as processed material as equivalent to original material deposited)	

**DEPOSIT STATEMENT**

**THIS FORM MUST BE COMPLETED IN ENGLISH**

[Our present policies are stated in Industrial Property No. 1, pp. 24-25 (1983)]

1. Name of Microorganism and Depositor's Strain Designation (acronym, sigla, abbreviation + number, symbols)

Cyan426, unidentified fungus

This microorganism is: a bacterium ☐, an *Actinomycetales* ☒, a mold ☐, a yeast ☐, an alga ☐, a strain containing recombinant DNA molecules ☐, a strain containing its own naturally occurring plasmid(s) ☐, a strain containing inserted naturally occurring plasmid(s) from another host ☐, a strain containing inserted constructed plasmid(s) a strain containing a virus of any kind ☐.

2. Is this strain being deposited under the Budapest Treaty? Yes ☒ No ☐

3. Name and Address of

Depositor: \* Ramunas Bigelis

Wyeth Research

Building 205, Room 407

401 North Middletown Road

Pearl River, New York 10965

- \* Viability test reports and other correspondence will be sent to above party. Our processed material from the original deposit will be sent to above party for checking. If there is no response within 3 months from date of shipment, our processed material will be considered equivalent to the original deposit in terms of viability and performance attributed to the strain.

4. Indicate the properties of the microorganism which are or may be dangerous to health or the environment, or indicate that the depositor is not aware of such properties.

To our knowledge, this strain is non-pathogenic.

5. Is this strain zoopathogenic? Yes ☐ No ☒ phytopathogenic? Yes ☐ No ☒

6. Recommended Conditions for Optimal Cultivation of the Microorganism and for Testing Its Viability:\*

potato dextrose broth, potato dextrose agar

\* Progeny of strains will be preserved at the Agricultural Research Service Culture Collection (NRRL) as lyophilized preparations, frozen preparations (liquid nitrogen vapor phase), or, in some cases, as agar slant cultures overlaid with mineral oil. All lyophilized or slant materials will be stored at 3-5°C.

7. \* Lowest permissible NIH\*\* (U.S.A.) Physical Containment level for processing and viability testing (P1, P2, P3, P4):  
Lowest permissible CDC\*\*\* (U.S.A.) Biosafety level for processing and viability testing (1, 2, 3, 4):

\* The Agricultural Research Service Culture Collection (NRRL) can, at present, process progeny of strains only at Physical Containment level P1 or Biosafety Level 1 or less.

\*\* U.S. Department of Health and Human Services, National Institutes of Health, Bethesda, Maryland 20205, U.S.A., November 1980. Guidelines for Research Involving Recombinant DNA Molecules.

\*\*\* U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Office of Biosafety, Atlanta, Georgia 30333, U.S.A. 1980. Proposed Biosafety Guidelines for Microbiological and Biomedical Laboratories.

8. Are you willing to waive the right to be informed of all requests for progeny of this strain? (This is allowed under the Budapest Treaty but will require additional correspondence.) Yes ☐ No ☒

9. I understand and agree that the deposit may not be withdrawn by me or any representative of my organization for the period specified in Rule 9.1 of the Budapest Treaty (at least 30 years after the date of accessioning).

Date: 10/29/02

Wyeth Research  
(on behalf of)

Signature of Depositor: Ramunas Bigelis

Ramunas Bigelis  
(Typed name of depositor)

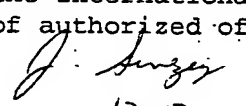
BUDAPEST TREATY ON THE INTERNATIONAL  
RECOGNITION OF THE DEPOSIT OF MICROORGANISMS  
FOR THE PURPOSE OF PATENT PROCEDURES

INTERNATIONAL FORM

TO  
Patent Dept.  
Wyeth Research  
401 North Middletown Rd.  
Pearl River, NY 10965

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT  
issued pursuant to Rule 7.1 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page

NAME AND ADDRESS  
OF DEPOSITOR

<b>I. IDENTIFICATION OF THE MICROORGANISM</b>	
Identification reference given by the DEPOSITOR: Unidentified fungus Cyan426	Accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY:  NRRL 30632
<b>II. SCIENTIFIC DESCRIPTION AND/OR PROPOSED TAXONOMIC DESIGNATION</b>	
The microorganism identified under I. above was accompanied by:  <input checked="checked" type="checkbox"/> a scientific description  <input type="checkbox"/> a proposed taxonomic designation  (Mark with a cross where applicable)	
<b>III. RECEIPT AND ACCEPTANCE</b>	
This International Depositary Authority accepts the microorganism identified under I. above, which was received by it on October 30, 2002 (date of the original deposit) <sup>1</sup>	
<b>IV. RECEIPT OF REQUEST FOR CONVERSION</b>	
The microorganism identified under I. above was received by this International Depositary Authority on (date of the original deposit) and a request to convert the original deposit to a deposit under the Budapest Treaty was received by it on (date of receipt of request for conversion).	
<b>V. INTERNATIONAL DEPOSITARY AUTHORITY</b>	
Name: Agricultural Research Culture Collection (NRRL) International Depositary Authority  Address: 1815 N. University Street Peoria, Illinois 61604 U.S.A.	Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s):   Date: 12-17-02

<sup>1</sup> Where Rule 6.4(d) applies, such date is the date on which the status of international  
depositary authority was acquired.

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT  
OF MICROORGANISMS FOR THE PURPOSE OF PATENT PROCEDURES

INTERNATIONAL FORM

TO  
Patent Dept.  
Wyeth Research  
401 North Middletown Rd.  
Pearl River, NY 10965

VIABILITY STATEMENT

issued pursuant to Rule 10.2 by the  
INTERNATIONAL DEPOSITARY AUTHORITY  
identified at the bottom of this page

NAME AND ADDRESS OF THE PARTY TO WHOM  
THE VIABILITY STATEMENT IS ISSUED

<b>I. DEPOSITOR</b>		<b>II. IDENTIFICATION OF THE MICROORGANISM</b>	
Name: Patent Dept. Wyeth Research Address: 401 North Middletown Rd. Pearl River, NY 10965		Depositor's taxonomic designation and accession number given by the INTERNATIONAL DEPOSITARY AUTHORITY: Unidentified mold NRRL 30632 Date of: October 30, 2002 <input checked="" type="checkbox"/> <sup>2</sup> Original Deposit <input type="checkbox"/> <sup>2</sup> New Deposit <input type="checkbox"/> <sup>2</sup> Repropagation of Original Deposit	
<b>III. (a) VIABILITY STATEMENT</b>			
Deposit was found: <input checked="" type="checkbox"/> Viable <input type="checkbox"/> Nonviable on November 1, 2002 (Date). International Depositary Authority's preparation was found viable on November 14, 2002 (Date) <sup>3</sup>			
<b>III. (b) DEPOSITOR'S EQUIVALENCY DECLARATION</b>			
Depositor determined the International Depositary Authority's preparation was <input checked="" type="checkbox"/> <sup>2</sup> Equivalent <input type="checkbox"/> <sup>2</sup> Not equivalent to deposit on <u>Oct 30, 2002</u> (Date) Signature of Depositor <u>Lamunas Bzdis</u> <u>5/13/03</u>			
<b>IV. CONDITIONS UNDER WHICH THE VIABILITY TEST WAS PERFORMED (Depositors/Depositary)<sup>4</sup></b>			
<u>Bennett's agar, malt extract agar</u>			
<b>V. INTERNATIONAL DEPOSITARY AUTHORITY</b>			
Name: Agricultural Research Culture Collection (NRRL) International Depositary Authority Address: 1815 N. University Street Peoria, Illinois 61604 U.S.A.		Signature(s) of person(s) having the power to represent the International Depositary Authority or of authorized official(s): <u>[Signature]</u> Date: <u>12-17-02</u>	

<sup>1</sup> Indicate the date of the original deposit or when a new deposit has been made.

<sup>2</sup> Mark with a cross the applicable box.

<sup>3</sup> In the cases referred to in Rule 10.2(a)(ii) and (iii), refer to the most recent viability test.

<sup>4</sup> Fill in if the information has been requested.

COMBINED DECLARATION AND POWER OF ATTORNEY  
(Original, Design, Supplemental, Divisional, Continuation, CIP)

As the below named inventor, I hereby declare that:

INVENTORSHIP IDENTIFICATION

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

TITLE OF INVENTION

**ANTIBIOTIC CYAN426-A**

SPECIFICATION IDENTIFICATION

the specification of which: (complete (a), (b), or (c))

- (a) ☒ is attached hereto.  
(b) ☐ was filed on \_\_\_\_\_ as  
          ☐ Application Number  
          ☐ Express Mail No. \_\_\_\_\_, as Application Number not yet known  
(c) ☐ was described and claimed in PCT International Application No. \_\_\_\_\_ filed  
          on \_\_\_\_\_ and as amended under PCT Article 19 on \_\_\_\_\_ (if any).

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37 CFR 1.56(a).

**PRIORITY CLAIM**

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119 of any foreign application(s) for patent or inventor's certificate or of any PCT International application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate of any PCT International application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) on which priority is claimed.

- (d) ☒ No such applications have been filed.  
(e) ☐ Such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. claimed priority, check item (e), enter the details below and make the priority claim.

Earliest Foreign Application(s), if any, filed within 12 months (6 months for Design) prior to this U.S. Application

Country	Application No.	Date of Filing (Day, Month, Year)	Priority Claimed 35 USC 119

All Foreign Application(s), if any, Filed More Than 12 Months  
(6 Months for Design) Prior to This U.S. Application)



CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)  
(35 U.S.C. § 119(E))

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

**PROVISIONAL APPLICATION NUMBER**

**FILING DATE**

60/434,005

December 17, 2002

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)  
(UNDER 35 U.S.C. 120)

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) designating the United States of America that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, Section 1.56(a) which occurred between the filing date of the prior application(s) and the national or PCT International filing date of this application.

**PRIOR U.S. APPLICATIONS OR PCT INTERNATIONAL APPLICATIONS  
DESIGNATING THE U.S. FOR BENEFIT UNDER 35 USC 120**

U.S. Applications		Status (Check One)		
U.S. Applications	U.S. Filing Date	Patented	Pending	Abandoned
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

PCT Applications Designating U.S.		
PCT APPLICATION NO.	PCT FILING DATE (Day, Month, Year)	U.S. APPLICATION NO. ASSIGNED (if any)

POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

☒ Customer Number: 25291

☐ Attached as part of this declaration and power of attorney is the authorization of the above-named attorney(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO:

Customer Number: 25291

DIRECT ALL TELEPHONE CALLS TO:


Name: Daniel B. Moran  
Tel. No. (845) 602-2224

DECLARATION

I hereby declare that all statements herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

Full name of SOLE OR FIRST INVENTOR: **Haiyin HE**

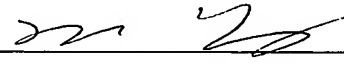
Inventor's Signature  Date 12/08/03

Country of Citizenship: **United States of America**

Residence : **189 Howard Street, Washington Township, NJ 07676**

Post Office Address: **Same as Residence**

Full name of SECOND JOINT INVENTOR: **Hui YANG**

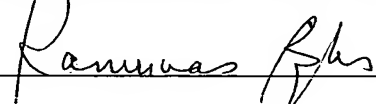
Inventor's Signature  Date 12/01/03

Country of Citizenship: **United States of America**

Residence : ~~83 Kearsing Parkway, Monsey, NY 10952~~ 243 Newport Ave, Tappan, NY 10983

Post Office Address: **Same as Residence**

Full name of THIRD JOINT INVENTOR: **Ramunas BIGELIS**

Inventor's Signature  Date 12/1/03

Country of Citizenship: **United States of America**

Residence : **192-8 N. Route 303, Congers, NY 10920**

Post Office Address: **Same as Residence**

Full name of FOURTH JOINT INVENTOR:

Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Country of Citizenship:

Residence :

Post Office Address: